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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,041	12/14/2005	Mark Roby	2873(203-3512	5860

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UNITED STATES SURGICAL,  
A DIVISION OF TYCO HEALTHCARE GROUP LP  
195 MCDERMOTT ROAD  
NORTH HAVEN, CT 06473

EXAMINER
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GILLESPIE, BENJAMIN

ART UNIT	PAPER NUMBER
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1711

MAIL DATE	DELIVERY MODE
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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/533,041	<b>Applicant(s)</b> ROBY, MARK	
	<b>Examiner</b> Benjamin J. Gillespie	<b>Art Unit</b> 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 14 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 13-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 13-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/23/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

1. Claims 7, 15, 19, and 24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 19 are rejected because the compounds listed as “trifunctional” have quad-, tri-, and di- functional groups, i.e. pentaerythritol, trimethylolpropane, and neopentyl glycol; therefore it is unclear what “trifunctional” means. The terms “approximating” and “approximated” render claim 15 indefinite because it is unclear what these terms mean. Claim 24 is rejected because “at least partially” is relative language.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, 6, 8-9, 13-18, and 20-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipatova et al ('535). Lipatova et al teach a tissue adhesive composition comprising (A) a bioabsorbable oligomeric ester compound that is end-capped with aromatic diisocyanate, (B) a trifunctional compound that is end-capped with aromatic diisocyanate, and (C) an aromatic diisocyanate (Col 1 lines 33-48, 66-67). Compounds (A), (B), and (C) exist in amounts that coincide with the ranges of claims 13 and 14, and the aromatic polyisocyanates (A) consist of 4,4'-diphenylmethane diisocyanate, naphthalene diisocyanate, and toluene

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diisocyanate, which correspond to the diisocyanates of claims 6, 8, and 9 (Col 1 lines 38-48; and col 2 lines 20-23).

3. Lipatova et al also teach a method of adhering a first and second tissue together via said composition, sealing a defect in tissue via said composition, wherein the seal prevents leakage of bodily fluids, and the composition is cross-linked through contact with water (Col 1 lines 24-26; col 4 lines 58-68; and col 9 lines 3-6).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 2-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipatova et al ('535) in view of English et al ('691). Aforementioned, Lipatova et al teach a tissue adhesive composition comprising bioabsorbable oligomeric ester that is end capped with aromatic diisocyanate, wherein the adhesive is applied to living tissue, cross-linked with water, and once the living tissue has healed the adhesive is broken down by hydrolysis and removed from the body (Col 2 lines 11-13). Patentees however fail to teach a bioabsorbable oligomeric composition that corresponds to the claims.

5. English et al teach a bioabsorbable tissue adhesive comprising polyester and aromatic diisocyanates, with the polyester backbone preferably derived from lactide, glycolide, and  $\epsilon$ -caprolactone and initiated by pentaerythritol or ethylene glycol (Col 2 lines 60-68; col 3 lines 1-19). Patentees go on to explain that these polymers have the advantage of acting as normal

constituents in metabolic pathways after being broken down by hydrolysis, and therefore are less toxic to the user (Col 2 lines 18-22).

6. Therefore it would have been obvious to one of ordinary skill in the art at the time of invention to utilize the polyesters of English et al in Lipatova et al based on the motivation that both teach bioabsorbable tissue adhesives based on polyester backbones and aromatic diisocyanates, and the polyester of English et al is less toxic for the user.

7. Claims 7, 19, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipatova et al ('535) in view of English et al ('691) and in further view of Guthrie et al ('323). Aforementioned, Lipatova et al in view of English et al render obvious a composition comprising a bioabsorbable oligomeric ester compound that is end-capped with aromatic diisocyanate, (B) a trifunctional compound that is end-capped with aromatic diisocyanate, and (C) an aromatic diisocyanate, wherein the isocyanate capped compound (A) has a functionality of two and the adhesive is broken down through hydrolysis. However, neither Lipatova et al nor English et al teach trifunctional compounds that correspond to those claimed by applicants.

8. Guthrie et al teach an adhesive comprising lactic and/or glycolic acid based polyester, which is end-capped with aromatic diisocyanates, and cross-links upon exposure to water (Col 3 lines 43-58; col 4 lines 32-34, 66-68; col 5 lines 9-27; col 6 lines 55-56). Furthermore, patentees explain that when the isocyanate-capped polyester has a functionality of only two, an isocyanate-terminated cross-linking agent is preferably included, wherein the agent consists of pentaerythritol, trimethylolpropane, and glycerol (Col 5 lines 19-25; col 7 lines 10-30). The cross-linking agent increases the degree of cross-linking in the composition resulting in a network having improved mechanical properties, and what's important to note is some of the

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cross-linking may occur before application of the adhesive or completely in-situ (Col 5 lines 23-27; col 7 lines 11-27). Furthermore, Guthrie et al teach that catalyst may be added during cross-linking in order to facilitate the release of CO<sub>2</sub> gas and permit room temperature curing (Col 9 lines 16-19; col 17 lines 16-18).

9. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the cross-linking agents of Guthrie et al in the composition of Lipatova et al in view of English et al because both teach the presence of isocyanate-capped trifunctional compounds, analogous isocyanate-capped polyester prepolymers, and the presence of the cross-linking agents improve the mechanical properties of the adhesive. Although the composition of Guthrie et al is not specifically drawn to binding two surfaces of living tissue, patentees teach the polyesters are based on the same reactants and the resulting adhesive can be broken down through hydrolysis. Therefore Guthrie et al is a relevant teaching based on analogous composition and properties.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipatova et al ('535) in view of English et al ('691) and in further view of Bennett et al ('130).

Aforementioned, Lipatova et al in view of English et al render obvious a composition comprising a bioabsorbable oligomeric ester compound that is end-capped with diisocyanate, (B) a trifunctional compound that is end-capped with diisocyanate, and (C) diisocyanate wherein the composition is cross-linked at room temperature in the presence of water and through the aid of triethylene diamine catalyst, chemically synonymous with 1,4-diazabicyclo[2.2.2]octane (Col 17 lines 15-18). However, patentees fail to disclose the amount of time needed for cross-linking.

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11. Bennett et al teach an adhesive comprising a (A) bioabsorbable oligomeric ester, (B) trifunctional compound, and (C) diisocyanate, wherein (A) and (B) are terminated with isocyanate groups (Abstract; col 3 lines 39-57; col 4 lines 37-60; col 5 lines 58-67). Important to note is that Bennett et al teach the adhesive composition is cross-linked through the aid of 1,4-diazabicyclo[2.2.2]octane, at a temperature between 20°C and 40°C, and as little as five minutes (Col 6 lines 22-37).

12. Although Bennett et al specifies that the selection of diisocyanate is important and certain aromatic diisocyanate should not be employed because of toxicity concerns, it still would have been obvious to utilize the cross-linking parameters of Bennett et al in the composition rendered obvious by Lipatova et al in view of English et al based on the motivation that Bennett et al do no limit certain diisocyanates, and the composition of Lipatova et al in view of English et al has been clearly disclosed for use as a living tissue adhesive and therefore is safe for in-situ applications. Another important note is that the both teach 1,4-diazabicyclo[2.2.2]octane as the cure catalyst, wherein the curing takes place in at the same temperatures, and the reactive species present during cross-linking, i.e. isocyanate groups and water, are the same.


### *Conclusion*

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin J. Gillespie whose telephone number is 571-272-2472. The examiner can normally be reached on 8am-5:30pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571-272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

B. Gillespie

  
**RABON SERGENT**  
**PRIMARY EXAMINER**